



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

11 MAY 2016

MEMORANDUM FOR ST

ATTN: KAREN L WEIS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled Pregnancy in the Military: Importance of Psychosocial Health to Birth Outcomes presented at/published to Scientific Panel, 2016 Military Women's Health Research Conference, USUHS, Bethesda, MD 25 April -27 April 2016 with MDWI 41-108, and has been assigned local file #16180.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS **USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING**

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). If you have any questions or concerns, please contact the 59 CRD/ Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). See 59 MDW 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

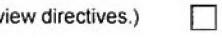
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, *Guide for the Care and Use of Laboratory Animals* and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Karen L. Weis, Col (ret), PhD		3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: FWH20120012H
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) Mentors Offering Maternal Support (M.O.M.S.): Building Resilient Families				
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Pregnancy in the Military: Importance of Psychosocial Health to Birth Outcomes				
7. FUNDING RECEIVED FOR THIS STUDY? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO FUNDING SOURCE: TSNRP				
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.				
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED. <input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.) <input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.) <input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) <input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.) <input checked="" type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) Scientific Panel, 2016 Military Women's Health Research Conference, USUHS, Bethesda MD, 25 April-27 April 2016				
12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).				
DATE April 25, 2016				
13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Walker, Katherine C. katherine.walker.ctr@us.af.mil			14. DUTY PHONE/PAGER NUMBER 292-6239	
15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.				
LAST NAME, FIRST NAME AND M.I. a. Primary/Corresponding Author Weis, Karen L.	GRADE/RANK PhD, Col (ret)	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW) Univ of Incarnate Word	
b.				
c.				
d.				
e.				
f.				
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.				
16. AUTHOR'S PRINTED NAME, RANK, GRADE Katherine Walker, CTR		17. AUTHOR'S SIGNATURE WALKER,KATHERINE.C.1457060	18. DATE April 19, 2016	
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Brenda J. Morgan, Col, 59 MDW/ST Acting Deputy Chief Scientist		20. APPROVING AUTHORITY'S SIGNATURE MORGAN,BRENDA.J.1135106085	21. DATE April 19, 2016	

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED April 19, 2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16180
24. DATE REVIEWED 19 Apr 2016	25. DATE FORWARDED TO 502 ISG/JAC	
26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES If yes, give date. 19 Apr 2016		<input type="checkbox"/> N/A
27. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The author added the appropriate DoD disclaimer statement to her abstract and presentation. Both are approved.		
28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	29. REVIEWER SIGNATURE  CALCOTE, ROCKY D.1178245844	30. DATE
2nd ENDORSEMENT (502 ISG/JAC Use Only)		
31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA	
33. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	35. REVIEWER SIGNATURE  CARWILE, CHRISTOPHER STEWART 1280477229	36. DATE
3rd ENDORSEMENT (59 MDW/PA Use Only)		
37. DATE RECEIVED May 06, 2016	38. DATE FORWARDED TO 59 MDW/SGVU May 06, 2016	
39. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Christopher Carwile, TSgt/E-6, NCOIC, PA	41. REVIEWER SIGNATURE  CARWILE, CHRISTOPHER STEWART 1280477229	42. DATE May 06, 2016
4th ENDORSEMENT (59 MDW/SGVU Use Only)		
43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
45. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED		
46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE	48. DATE

PRENATAL PSYCHOSOCIAL HEALTH AND BIRTH OUTCOMES IN A MILITARY POPULATION

Keywords: Prenatal Maternal Anxiety, Early Gestational Age, Infant Birth Weight, Military

Background: Maternal psychological health has received increased attention because of the connection of prenatal anxiety to higher rates of spontaneous abortion (Nakano et al., 2004), preterm birth (Roy-Matton, Moutqui,, Brown, Carrier, & Bell, 2011), and low infant birthweight (Rondo et al., 2003). Prenatal depression has been linked to higher incidences of preterm birth (Dayan et al., 2006), decreased maternal attachment and sensitivity (Siddiqui & Hagglof, 2000), and cognitive delays in childhood (Pearson et al., 2013). Studies within the military community are limited. **Purpose:** Describe findings across a program of research dedicated to prenatal maternal psychosocial health to birth outcomes for a military population. **Methods:** Longitudinal design of repeated measures using the Social Support Index (SSI), the Lederman Prenatal Self-Evaluation Questionnaire (PSEQ), Edinburgh Prenatal Depression Scale (EPDS) and FACES II were provided to the participants in each trimester of pregnancy (across multiple studies). Subjects were various samples, one of 421 women from San Antonio area military health system and another of 300 women of mixed parity, all military beneficiaries, either active duty or dependant wives receiving prenatal care at Wilford Hall Ambulatory Surgical Center. **Findings:** Hierarchical linear regression models were used to assess the anxiety experienced prenatally on infant birth weight and early gestational age. Anxiety related to Acceptance of Pregnancy ($\beta = -0.15; p \leq 0.001$), Identification of the Motherhood Role, Preparation for Labor ($\beta = 0.20; p \leq 0.001$), Well-Being of Self and Infant ($\beta = 0.12; p \leq 0.001$) were predictive of early gestational age. Anxiety related Helpless and Loss of Control ($\beta = 0.07; p \leq 0.01$) and Preparation for Labor ($\beta = -0.05; p \leq 0.05$) were predictive of low infant birthweight. These findings together with others formed the development of the Mentors Offering Maternal Support (M-O-M-S) program. **Discussion:** The findings provide convincing evidence that similar to civilian populations, military women experience prenatal anxiety that does effect birth outcomes. The findings indicate a need for early prenatal intervention designed for a military population.

- The opinions expressed in this presentation are solely those of the author and do not represent the views of the Department of Defense, or the United States Government



This correction letter replaces the approval letter dated 6 Feb 12

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
LACKLAND AIR FORCE BASE TEXAS

24 Feb 12

FINAL IRB APPROVAL (FULL BOARD - MINIMAL RISK)

Approval Date: 22 Nov 11

Principal Investigator: Col Karen Weis / SGN

IRB Reference Number: FWH20120012H

Assurance Number: FWA00001750 (Wilford Hall Ambulatory Surgical Center)

Protocol Title: "Mentors Offering Maternal Support (M.O.M.S.): Building Resilient Families"

1. Your study, referenced above, is approved for **one year** as a **MINIMAL RISK** study by the Wilford Hall Ambulatory Surgical Center's Institutional Review Board (WHASC IRB). Additional items reviewed and approved by the WHASC IRB include:

PI Attachment 1 - Centering Pregnancy program overview
PI Attachment 2 - M.O.M.S. Mentor Training Agenda
PI Attachment 3 – "Birth of a Mother" Guide
PI Attachment 4.1. Demographic Questions for M.O.M.S.
PI Attachment 4.2. Demographic Questions for Husband
PI Attachment 5 - Welcome Letter to M.O.M.S. (script)
PI Attachment 6.1. Handout for M.O.M.S Participants
PI Attachment 6.2. Handout for Husbands of M.O.M.S.
PI Attachment 7.1. M.O.M.S. participant ICD
PI Attachment 7.2. Husband participant ICD
PI Attachment 8.1. Prenatal Self-Evaluation Questionnaire II (PSEQ) Instrument
PI Attachment 8.2. Maternal Antenatal Scale (MAAS) Instrument
PI Attachment 8.3. Rosenberg Self-Esteem Scale Instrument
PI Attachment 8.4. Family Adaptability and Cohesion Evaluation Scales II (FACES) Instrument
PI Attachment 8.5. COPE Instrument
PI Attachment 8.6. Edinburgh Postnatal Depression Scale (EPDS) Instrument
PI Attachment 9 - High Risk Screening Tool
PI Attachment 10 - Semi Structured Interview Questions for Husbands
PI Attachment 11 - Study Timeline
PI Attachment 12 - M.O.M.S. Satisfaction Questionnaire
PI Attachment 14 - Budget and External Funding Support
PI Attachment 17 - HIPAA Authorization Document

2. Your study will be reviewed in **11 months for continuing review, based on its approval date, not to exceed 365 days.** It is the WHASC IRB's decision that this study will be terminated as of 21 Nov 12, unless you submit a continuing review report, using the template provided by the Protocol Office. Your first progress report, which is a request for continuation of the study, will be due to the Protocol Office no later than 1 Oct 12. A continuing review report will be due every **11 months** thereafter, in order for the WHASC IRB to approve continuance of the study for another year. Upon completion of your study you must submit a final closeout report to the WHASC Protocol Office.

3. Following IRB review/approval, it is the PI's responsibility to ensure the Institutional Official (IO) or Authorized Institutional Official (AIO) provides written authorization to implement the study at their respective facility or facilities (if a multi-site protocol), in accordance with AFI 40-402, Section 2.5.5. This written authorization(s) must be forwarded to the WHASC Protocol Office before implementing your study (if applicable). The AIO approval memo must be received by the WHASC Protocol Office within 30 days of IRB review/approval notification, or the study will be withdrawn with no further action. Upon receipt of the AIO approval memo, the WHASC Protocol Office will issue a final study implementation letter, plus an original date-stamped ICD and any other IRB-approved documents needed for the study.

4. Only investigators listed below are approved to participate in the study (e.g., obtain consent and to interact with and/or collect identifiable information on research subjects):

- Col Karen L Weis, PI
- Lt Col Candy Wilson, AI
- Lt Col Brenda Morgan, AI
- Lt Col Regina Paden, AI
- Lt Col Nicole Armitage, AI
- Candice Hamel, Research Assistant / Coordinator

These are the only investigators identified by the WHASC IRB to have completed "IRB approved" investigator training. Any additions to this list must first be approved by the IRB by submitting an amendment, along with a copy of the investigator's training certificate.

5. Your MINIMAL RISK study will be forwarded to the Surgeon General's Research Compliance and Oversight Office (AFMSA/SGE-C) for information and concurrence.

6. The WHASC IRB must be notified immediately of any additional information, or changes to the protocol. All amendments to either the protocol or ICD must be reviewed and approved by the WHASC IRB prior to their inception.

7. You must comply with the information contained in the Certificate of Compliance.

8. If funds were requested for your study, you will be notified by the 59th Clinical Research Division Resource Manager (292-7924) concerning the status of the requested funds. YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.

9. If you have any questions, the POC is Protocol Office Staff at (210) 292-4012/292-6095/292-7143. Please include your project title and reference number in all correspondence or inquiries.

Rocky Calcote
ROCKY CALCOTE, PhD
Clinical Research Administrator

Prenatal Psychosocial Health and Birth Outcomes in a Military Population

Karen L. Weis PhD, RNC, FAAN
University of the Incarnate Word

Acknowledgements

Projects funded by:

U.S. DoD TriService Nursing Research Program

MDA-905-00-1-0039

HU0001-1101-TS 13



UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

Disclosures

- No financial disclosures or conflict of interest
- The opinions expressed in this presentation are solely those of the author and do not represent the views of the Department of Defense, or the United States Government

Introduction

- Prenatal maternal anxiety is predictive of:
 - Early gestational age (EGA)
 - Lower birth weights (LBW)
 - Higher rates of childhood illness
 - Physical and cognitive developmental delays
- Prenatal depression is linked to LBW, EGA and poor maternal attachment

Military Findings

- Followed 501 military women thru pregnancy
- Prenatal maternal anxiety was predictive of:
 - Early gestational age
 - Lower birth weights
 - Poor maternal-infant attachment
 - Lower maternal role satisfaction



UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

Pregnancy-Specific Anxiety

- Acceptance of Pregnancy ($p < .001$)
- Identification with Motherhood ($p < .001$)
- Preparation for Labor ($p < .01$)
- Well-Being of Self and Infant ($p < .001$)

- Preparation for Labor ($p < .05$)
- Fears of Helplessness ($p < .01$)

Early
Gestational
Age

Low
Birth
Weight

Differences in AD/non-AD

Statistically significant differences for:

- Acceptance of pregnancy ($p=.03$; $p=.01$)^{1,3}
- Preparation for labor ($p=.04$)¹
- Relationship with husband ($p=.04$; $.02$; $.01$)^{1,2,3}

Anxiety greatest in AD and highest in the sample of AD Army women

Planned vs Unplanned Pregnancy

Status	Planned	Unplanned
Active Duty (n=96)	46.9%	53.1%
NonActive Duty (n=149)	65.1%	34.9%

Significantly higher anxiety for unplanned pregnancies:

- 1st trimester, Acceptance, $F(1,231) = 22.86, p = .000$
- 2nd trimester, Acceptance, $F(1,231) = 12.64, p = .000$
- 3rd trimester, Acceptance, $F(1,231) = 7.32, p = .007$

Postpartum Depression Statistics

Military Surveillance data (Do et al., 2013):

- 8.2% of service women diagnosed with PPD
- AD service women had increase in diagnosis for each year of study
- Highest rates in Army (12%) and lowest in Air Force (7.3%)
- Reports indicate higher rates for PPD in military than in civilian population



UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

Prenatal Depression

2 nd Trimester	N	Mean	SD	Min	Max
NonAD	147	4.25	3.87	.00	17.00
Air Force	67	3.99	3.91	.00	21.00
Army	24	8.25	5.47	1.00	24.00
Navy	2	7.00	5.66	3.00	11.00
Marine	2	5.50	3.54	.00	24.00

Note: Depression measured with EPDS

10 items with 0-3; higher scores indicating > depression

Depression significant factor for increased anxiety
for acceptance of pregnancy, well-being in pregnancy &
relationship with husband

Issues Unique to Military (Prenatal Anxiety & Depression)

- Service before self
 - Attitude present in family as well as service member
 - Sacrifice everything for the mission
 - Profound pressure to support spouse
 - Spouse very involved in work; hesitant to ask for help
- AD women – concerns for ramifications of pregnancy on career

Psychosocial Health in Pregnancy

- Anxiety related to pregnancy-specific factors and/or depression do not decrease without intervention
- Military has 1.16 million medical encounters/yr for pregnancy complications -- #3 being “other threatened labor” & #5 “threatened premature labor”



Ongoing Work

- Testing effectiveness of Mentors
- Offering Maternal Support intervention
- Psychosocial health and placental effects being assessed with biomarkers
- Effectiveness of interventions on birth outcomes and long-term benefits requires longitudinal studies of large numbers



UNIFORMED SERVICES UNIVERSITY
of the Health Sciences